K032098

OCT - 7 2003

510(k) Summary

510(k) Number:
Company: Arthrex, Inc.
Address: 2885 S. Horseshoe Dr., Naples, FL 34104
Telephone: (239) 643-5553
Facsimile: (239) 430-3494
Contact: Ann Waterhouse

Trade Name: Arthrex Bio-Compression Screw
Common Name: Fastner, Fixation, Degradable
Classification: Class II
Product Code: MAI

Description:

The Arthrex Bio-Compression Screw is manufactured using poly(L-lactide). These are offered sterile, in distinct sizes. Further description is contained in Tab 6.

Indications for Use:

The Arthrex Bio-Compression implant is a bioabsorbable polylactide (PLLA) screw intended to provide fixation of small bone fragments such as apical fragments, osteochondral fragments, and cancellous fragments. Specifically;

Apical Fragments: Radial Head, Patellar Rim, Navicular, Metacarpal and Metatarsal
Osteochondral Fragments: Talar Vault, femoral condyle
Cancellous Fragments: Talus

Predicate Devices:

Please see Tab 7 for specific information concerning predicate devices.

Substantial Equivalence:

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The difference between the Arthrex Bio-Compression Screw and the predicate devices with similar indications do not raise any questions regarding the safety and effectiveness of the implant. Furthermore, the material is well characterized and has been used in predicate devices with similar indications. The device, as designed, is as safe and effective as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 2003

Ms. Ann Waterhouse
Regulatory Affairs Specialist
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K032098
Trade/Device Name: Bio-Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 7, 2003
Received: July 9, 2003

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name:

Indications for Use:

The Arthrex Bio-Compression Screw is a bioabsorbable polylactide (PLLA) screw intended to provide fixation of small bone fragments such as apical fragments, osteochondral fragments, and cancellous fragments. Specifically;

Apical Fragments: Radial Head, Patellar Rim, Navicular, Metacarpal and Metatarsal

Osteochondral Fragments: Talar Vault, femoral condyle

Cancellous Fragments: Talus

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Option Format 3-10-98)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032098

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